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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,331	07/11/2003	Laurence Du-Thumm	IR 7050-00	5282

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/618,331	Applicant(s) DU-THUMM ET AL.	
	Examiner Frederick Krass	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 16-18, 20-27 and 29-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 16-18, 20-27 and 29-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>20061205</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Previous Rejections

Unless specifically maintained infra, all previous rejections are withdrawn.

Obviousness Rejection

1) Claims 11, 16-18, 20-24, 26-42 and 44-46 were rejected under 35 USC 103(a) as being unpatentable over Gebresselassie et al (USP 6,379,654) in view of Wagenknecht et al (USP 4,148,872).

This rejection is maintained.

2) Claims 25 and 43 were rejected under 35 USC 103(a) as being unpatentable over Gebresselassie et al (USP 6,379,654) in view of Wagenknecht et al (USP 4,148,872), the combination being taken further in view of Andersen et al (USP 5,487,902).

This rejection is maintained.

Discussion**1) Response to Applicant's Arguments**

Applicant argues that there is no motivation to combine the teachings of Gebreselassie et al, which teaches stable paste or gel formulations with an enzyme stabilizing agent and certain level of water to provide a certain pH range for stabilizing and optimizing enzymes, with Wagenknecht et al, which teaches tablet formulations with low levels of water (such that there would be no concern with stabilization of enzymes) to arrive at the presently claimed invention. (Remarks, page 7, third paragraph).

Furthermore, even if such motivation existed, no expectation of success would exist because it would be impossible to incorporate an enzyme into a confectionary composition, because the optimal pH value could not be achieved in the manner taught by the secondary reference in a chewing gum formulation versus a paste or gel formulation; rather, one would expect the combination of the two references to yield as composition with extremely unstable enzyme activity which would be ineffective in delivering antiplaque activity to the oral cavity. (At best, the product would be an enzyme containing compound where the enzyme was highly unstable, because the amounts of water would be insufficient to create an optimal pH range). (Remarks, page 8, first paragraph).

And finally:

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The present invention points out the importance of minimizing water content in chewable confectionary compositions (Specification, page 8, line 23 to page 9, line 3). Therefore, as shown, the presently claimed invention provides an unexpectedly stable formulation in chewable confectionary form in the presence of a minimum of water. (Remarks, page 8, second paragraph).

These arguments are not persuasive.

Contrary to Applicant's assertions, column 5, lines 2-15 of the primary reference make no mention of water content. That the working examples all include a water content of 15 percent or greater, as further argued by Applicant, is not conclusive since the disclosure of a patent is not limited to its working examples. Similarly, the observation made by patentees at column 3, lines 24-27 concerning the optimum pH range for enzymatic activity does not include any discussion of water content. Thus, while Applicant's analysis seems plausible, it is not clear that the primary reference disclosure is limited in the manner so argued.

Applicant's arguments are thus viewed as a "piecemeal" analysis which emphasize the individual deficiencies of each reference while ignoring what is suggested by their combined disclosures taken as a whole. There is no factual evidence of record to suggest that enzymes in chewing gums would not benefit from the modification outlined in the examiner's rejection. (Furthermore, Applicant's analysis does not take into account the fact that when the gum is chewed active agents contained therein would be released to an aqueous environment (saliva), where they would suffer the same stability problems as in a liquid dentifrice).

There is no factual evidence of record to suggest that a water content of less than 5 percent by weight represents an unusual water content for a chewing gum, or that

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lowering the water content of a chewing gum is an unusual procedure in the art. *See, e.g.*, Thorengaard et al (US Pub. 2005/0175733) at paragraph [0042]. *See also* USP 2,323,102 at the passage bridging column 1, line 16 to column 2, line 9, which demonstrates that the necessity to control water content to optimize product performance in the chewing gum art has long been recognized.

2) Details of Interview Summary

Applicant's representative and the examiner engaged in a telephonic interview on or about December 6, 2006 in an attempt to move prosecution forward. The examiner agreed that the claims could be placed in condition for allowance if the following events were to occur:

a) independent claim 11 was amended to recite "wherein the enzyme in said chewable confectionary composition maintains its activity over at least a 4 week period when stored at 23 degrees C" (see page 12, lines 4 and 5 of the instant specification);

b) independent claim 11 was amended to incorporate the limitation of instant claim 30 (because the specification states at page 8, lines 27-31 that processing at less than 80 degrees C is "critical" to obtaining improved stability); and

c) factual evidence, preferably in the form of a side-by-side comparison, was provided to corroborate Applicant's allegations that the stability outlined in subsection "a)" supra was indeed unexpected.

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Action is Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached on Monday through Friday from 9:30AM to 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marschel Ardin, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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